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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,968	02/13/2002	Heinrich Wieland	70301/56970	6225

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,968

Applicant(s)

WIELAND ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) 46 and 49-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-39, 47, 48 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The amendment filed May 18, 2004 has been entered.

Election/Restrictions

Claims 27-39 and 46-53 are pending. Claims 46 and 49-52 stand withdrawn as being directed to non-elected inventions. Applicant requests that the non-elected claims be rejoined because the amended claims are now directed to cosmetic treatments and method claim 46 and composition claims 49-52 also follow a cosmetic concept. This argument is not found persuasive because the composition of claims 49-52 has medical uses such as the treatment of atherosclerosis, thrombosis and myocardial infarction (see Grainger US 5,770,609) which are distinct from the claimed uses. The method of claim 46 is drawn to a method of decreasing hair growth which requires the application of a preparation to a body part having hair. A method for treating wrinkles requires application to skin. These steps are not overlapping because one does not generally want to remove wrinkles from hairy areas. Therefore, the methods are distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims drawn to an invention nonelected with traverse in the paper filed February 19, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 27-39, 47, 48 and 53 are pending.

Response to Arguments

Applicant's arguments filed May 18, 2005 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 27-31, 34 and 38 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 6,071,526.

Applicant argues that '526 claims a method of treating cellulite such that the subcutaneous connective fatty tissue disturbances are improved. Applicant asserts that the instant specification discloses the treatment of cellulite in '526 is directed to the fatty connective tissue of the subcutis while this instant claims are directed to the parts of the body that contains collagen such as the cutis.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the instant claims are directed to treating collagen in the cutis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, even if the instant claims recited a limitation of treating collagen in the cutis, such a limitation would not distinguish the instant claims from those of '527. Bessette et al. (US 6,920,883) discloses that skin has a layered structure comprising the outer dermis, the dermis and the inner subcutis. The dermis contains collagen and the subcutis lies below the dermis and consists of a network of collagen and fat cells. According to Taber's Cyclopedic Medical Dictionary, the term "cutis" is a synonym for "dermis" (p. 1570, right column, 1st paragraph). Therefore, practicing the method of '527 inherently practices the claimed method because the treatment agent is absorbed by the skin and passes through the cutis and into the subcutis. Collagen present in the cutis, just like collagen in the underlying subcutis, would inherently experience the same effect of the agent. The citation of Bessette et al. and Taber's are not new grounds of rejection. They were cited only to rebut Applicant's argument regarding how the agent would affect collagen in the cutis.

Claim Rejections - 35 USC § 102

Claims 27-39 and 53 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schmidt et al. (US 5,945,109).

Applicant argues that Schmidt is directed only to subcutaneous connective fatty tissue and there is no suggestion in the stabilization, increase or restoration of collagen. Applicant asserts that the Examiner's reference to the MPEP 2112.02 does not apply because one skilled in the art would not treat a patient for the indication of the present invention based on the teachings of Schmidt. Applicant further asserts that one would not necessarily obtain the instantly claimed results even if one practiced the method of Schmidt because the treatment of Schmidt is for a different purpose than that of the instant application (i.e. for cosmetic treatment). Applicant argues that the present invention can require a different application mode, different effective amount or a different amount of time to achieve the desired results.

Responding to Applicant's argument that Schmidt is directed only to subcutaneous connective fatty tissue and there is not suggestion in the stabilization, increase or restoration of collagen, the structure of skin causes the practice of the method of Schmidt anticipate the claimed method. Bessette et al. (US 6,920,883) discloses that skin has a layered structure comprising the outer dermis, the dermis and the inner subcutis. The dermis contains collagen and the subcutis, which lies below the dermis, consists of a network of collagen and fat cells. According to Taber's Cyclopedic Medical Dictionary, the term "cutis" is a synonym for "dermis" (p. 1570, right column, 1st paragraph). Therefore, practicing the method of '527 inherently practices the claimed method because the treatment agent is absorbed by the skin and passes through the cutis and into the subcutis. Collagen present in the cutis, just like collagen in the underlying subcutis, would inherently experience the same effect of the agent. The citation of Bessette et al. and Taber's are not new grounds of rejection. They were cited only to rebut Applicant's argument regarding how the agent would affect collagen in the cutis.

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Responding to Applicant's argument that the MPEP recitation does not apply because one skilled in the art would not treat a patient for the indication of the present invention based on the teachings of Schmidt are not directed to a cosmetic purposes and that Schmidt is directed to the treatment of cellulite for improving the appearance of a body region having cellulite. Schmidt states, "The cosmetic effect is effective in the cosmetic treatment of cellulite" (abstract of '526). Schmidt also discloses that "During use of the cosmetic product, or of the cosmetic, which inhibits formation and/or action of estrogens in the treated cutaneous fatty tissue zones, the skin surface becomes increasingly smooth and firm (col. 3, lines 12-18 of '526). Thus, Schmidt teaches that his treatment is cosmetic and directed to improving the appearance of skin by stabilizing the collagen. Again, due to the structure of skin, *supra* collagen present in the cutis, just like collagen in the underlying subcutis, would inherently experience the same effect of the agent.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the present invention can require a different application mode, different effective amount or a different amount of time to achieve the desired results) are not recited in the rejected claim(s).

Claims 27 and 28 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fritz et al. (Endocrine (1998) 139(8): 3399).

Claims 27 and 28 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Grainger et al. (US 5,770,609).

Claims 27 and 28 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nikura et al. (US 5,254,594).

Claims 27 and 28, stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sannti et al. (US 5,972,921).

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Applicant argues that neither Fritz et al, Grainger et al., Nikura et al. not Sannti et al. anticipate the claimed invention because said references are directed to therapeutic applications and not the currently claimed cosmetic applications. Applicant asserts that there is no inherency and that none of the references teaches or suggests a method for stabilizing, increasing or restoring collagen.

In response to applicant's arguments, the recitation "for cosmetic treatment" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, there is no recitation in the body of the claims that distinguishes the practice of the steps of the claimed method to that of the prior art. The prior art teaches the administration of a treatment that will encounter collagen in the treated body and, due to the properties of the treatment agent, said agent will inherently stabilize said collagen.

Claims 27, 28, 37-49, 47 and 48 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tanabe et al. (US 6,455,517).

Applicant argues that Tanabe teaches therapeutic and not cosmetic application and that assertion is confirmed by the fact that patients who were suffering from UV-caused damage from the sun leading to dermal atrophy were excluded from the treatment. Applicant concludes that there is not teaching or suggestion in Tanabe for a method of stabilizing, increasing or restoring collagen.

Responding that Tanabe does not teach the use of anti-estrogen treatments for cosmetic reasons, Applicant is directed to Tanabe, col. 83, lines 46-52, that the first component in the study is the evaluation of improvement in a patient's appearance due to the treatment. Cosmetic treatment is for the improvement of appearance. Thus, the disclosed treatment is therapeutic and cosmetic. Regarding

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Applicant's assertion that patients suffering from UV-damage were excluded from the study, Tanabe was evaluating skin atrophy strictly due to post-menopausal effects. This disclosure does not teach away from the treatment of dermal atrophy due to sun exposure with anti-estrogen agents because Tanabe teaches that sun exposure results in the same skin atrophy effects as post-menopausal effects. Responding to Applicant's argument that Tanabe does not inherently teach the claimed effects of stabilizing, increasing or restoring collagen, Tanabe teaches the administration of a treatment that will encounter collagen in the treated body and, due to the properties of the treatment agent, said agent will inherently stabilize said collagen.

Claim Rejections - 35 USC § 103

Claims 27, 28, 37-39, 47 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tanabe et al. (US 6,455,517).

Applicant argues that there is not teaching or suggestion in Tanabe for a method of stabilizing, increasing or restoring collagen and that Tanabe merely teaches compounds that can be used to replace conventional Tamoxifen chemotherapy.

Responding to Applicant's argument that Tanabe does not inherently teach the claimed effects of stabilizing, increasing or restoring collagen, Tanabe teaches the administration of a treatment that will encounter collagen in the treated body and, due to the properties of the treatment agent, said agent will inherently stabilize said collagen. Tanabe et al. identify Tamoxifen as a well known anti-estrogen that has the same effects as the claimed 1, 3, 5-estratriene compounds and use it as a standard to compare anti-estrogenic activity (co. 80-81 of the referenced patent). Tanabe does not limit the testing of his Tamoxifen analogs to chemotherapy, but evaluated them against Tamoxifen for dermal atrophy *supra*.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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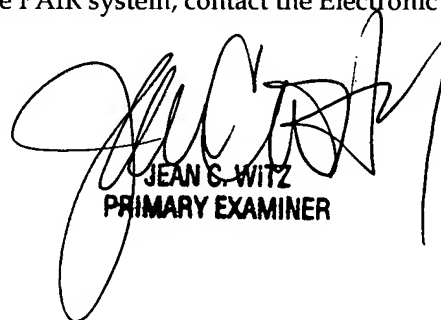
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
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JEAN S. WITZ
PRIMARY EXAMINER